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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,899	04/16/2004	John J. Allen	LFS-5010	8960

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EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/825,899

Applicant(s)

ALLEN ET AL.

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 10-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8, 9 and 13 is/are rejected.
- 7) ☒ Claim(s) 5-7 and 14 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/16/04, 8/26/05, 3/20/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species:

Species I, as shown in Fig. 1, is directed towards an apparatus comprising a clamping mechanism having a lower arm assembly and an upper arm assembly.

Species II, as shown in Fig. 9, is directed towards an apparatus comprising a clamping mechanism having a lever and an inner compression surface.

The species are independent or distinct because they do not overlap in scope (different clamping mechanisms); are not obvious variants, and are not capable of use together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

2. During a telephone conversation with Mayumi Maeda on 03/23/2007 a provisional election was made without traverse to prosecute the invention of Species I, claims 1-9, 13 and 14. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

4. The information disclosure statements (IDS) submitted on 04/16/2004, 08/26/2005 and 03/20/2006 have been received and made of record. Note the acknowledged forms PTO-1449 enclosed herewith.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. Claims 1-4, 8 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by US 3,626,929 to Sanz et al.

(claim 1) Sanz discloses an apparatus for extracting bodily fluid, the apparatus comprising:

a housing **1**;

a lancing mechanism **38a,38b** for lancing a target site attached to the housing (via blood sampling tube of device **15**)

a clamping mechanism attached to the housing, the clamping mechanism including:

a lower arm assembly or device **15**; and

an upper arm assembly (or shackle) **8**;

wherein the lower arm assembly and upper arm assembly are operatively connected such that a when a user's finger applies a predetermined user force to the lower arm assembly (the step of mounting device **15** into mounting **12**), the lower arm assembly **15** is displaced from a first position (Fig. 2) to a second position (Fig. 3),

wherein the upper arm assembly **8** and lower arm assembly **15** cooperate to engage the user's finger with a compressive force (along with block **6**; col. 6, lines 35-47) that is greater than the predetermined user force (since the predetermined user force is merely the force required to mount device **15** into mounting **12**), and

wherein the lancing mechanism **38a,38b** is configured to lance a target site on the user's finger while the upper arm assembly and lower arm assembly are cooperating to engage the user's finger (as shown in Fig. 4), whereafter the compressive force is

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fully capable of extracting a bodily fluid sample from the lanced target site (col. 6, lines 35-47).

(claim 2) As disclosed in col. 6, lines 49-55, the lower arm assembly and the upper arm assembly cooperate via a mechanical advantage (along with block 6) to provides a massaging compressive force.

(claim 3) A portion of the clamping mechanism is pivotably connect via pivot 7 and is capable of one-handed operation.

(claim 4) The lower assembly includes a pressure ring or funnel and the upper arm assembly includes a compression surface 9.

(claim 8) The apparatus includes a linking arm 17 that is operatively connected to the lower arm assembly and the upper arm assembly during various stages of the operation of the device.

(claim 13) Sanz also discloses a method for extracting bodily fluid from a target site, the method comprising:

providing an apparatus for extracting bodily fluid including:

a housing 1;

a lancing mechanism 38a,38b for lancing a target site attached to the housing (via blood sampling tube of device 15)

a clamping mechanism attached to the housing, the clamping mechanism including:

a lower arm assembly or device 15; and

an upper arm assembly (or shackle) 8;

applying a predetermined force to the lower arm assembly with a user's finger (during the step of mounting device **15** into mounting **12**) such that the lower arm assembly is displaced from a first position (Fig. 2) to a second position (Fig. 3),

wherein the upper arm assembly **8** and lower arm assembly **15** cooperate to engage the user's finger with a compressive force (along with block **6**; col. 6, lines 35-47) that is greater than the predetermined user force (since the predetermined user force is merely the force required to mount device **15** into mounting **12**), and

and lancing a target site on the user's finger while the upper arm assembly and lower arm assembly are cooperating to engage the user's finger, whereafter the compressive force is fully capable of extracting a bodily fluid sample from the lanced target site (col. 6, lines 35-47).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sanz et al.

Sanz discloses the claimed invention except for the predetermined user force is less than approximately 6N and the compressive force is between 9N and 18N. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the predetermined force be less than 6N, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Furthermore, the predetermined user force is merely the force required to seat device 15 into mounting 12.

It also would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at a compression force between 9N and 18N, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Allowable Subject Matter

10. Claims 5-7 and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The prior art of record fails to teach and/or render obvious the overall claimed invention of an apparatus for extracting bodily fluid, the apparatus comprising, inter alia, a means for limiting the compressive force. Furthermore, it should be noted that

according to *In re Donaldson Co.*, 16 F.3d 1189, 1193, 29 USPQ2d 1845, 1848 (Fed. Cir. 1994), the proper construction of a means-plus-function claim limitation requires interpreting the limitation in light of the corresponding structure, material, or acts described in the written description, and equivalents thereof, to the extent that the written description provides such disclosure. Therefore, the means for limiting the compressive force is viewed as the means recited in claims 6 and 7.

Conclusion

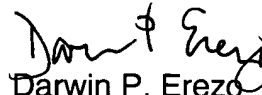
12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Darwin P. Erez
Examiner
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